

***ATX-MS-1467 - Positive Immunological data in Multiple Sclerosis  
Final Phase I/IIa data shows safety and tolerability, plus efficacy***

**Bristol, UK – 30<sup>th</sup> January, 2008, Apitope Technology (Bristol) Ltd.**, the developer of peptide-based therapies for autoimmune diseases and allergy, announces today final results of a Phase I/IIa clinical trial of ATX-MS-1467 to treat Multiple Sclerosis (MS). Immunological analyses showed a significant down regulation of the T-cell response to the autoantigen (myelin basic protein) whilst the important normal immune responses were left unchanged.

As previously announced, the therapeutic peptide vaccine was found to be safe and well tolerated in Secondary Progressive Multiple Sclerosis (SPMS) patients with no treatment related serious adverse or adverse events reported.

Although the trial was not designed to show efficacy, there is preliminary evidence of a positive clinical response to ATX-MS-1467 in two of the six patients. One patient with optic neuritis resulting from the neuroinflammatory process involved in MS continues to demonstrate a clinically significant improvement in visual acuity post treatment. Additionally, a second patient has shown improvement in the Gd-enhanced MRI scan indicating a reduction in neuroinflammatory processes in the brain.

“We are extremely pleased with these results in secondary progressive MS patients. The peptides are very well tolerated in this patient group”, said Dr Keith Martin, CEO of Apitope. “Also, we now have good indicators that these peptides may be a significant improvement on current therapies available to patients with MS, a disease with huge unmet medical need.”

The immunological analyses showed a reduction of up to 40% in myelin basic protein-induced T-cell proliferation one month after the course of treatment with ATX-MS-1467 while the T-cell response to PPD (a constituent of the BCG vaccine) was unchanged.

“These preliminary clinical and immunological data are very encouraging and support the preclinical and scientific evidence on which this product is based”, said Professor David Wraith, CSO of Apitope and Professor of Experimental Pathology at the University of Bristol.

Apitope expects to begin a final Phase II trial of ATX-MS-1467 before the fourth quarter this year with full results expected within 24 months of the trial start. This trial will be designed as a double-blind placebo controlled study in MS patients with the more frequently encountered relapsing remitting form of MS.

Along with development of ATX-MS-1467 Apitope is continuing development of a diagnostic blood test for MS and expects to complete the clinical validation in patients with all forms of MS in the next 12 months.

ATX-MS-1467, is a vaccine containing four peptides derived from human myelin basic protein that targets the major histocompatibility complex (MHC) class II molecule and has been specifically designed and developed to treat MS patients. The recently completed ATX-MS-1467 Phase I/IIa open label trial was designed as a dose escalation study to assess the safety and tolerability with all six patients receiving five escalating doses given 7 to 14 days apart of 25, 50, 100, 400 and 800 followed by a repeat of the 800 µg dose.

## **ABOUT APITOPE TECHNOLOGY (BRISTOL) LTD**

Apitope is a biopharmaceutical company engaged in the research and development of treatments for allergy and autoimmune diseases. The Company is developing novel advantaged products representing major advances in therapy and addressing critical unmet needs that can revolutionise the treatment of chronic autoimmune and allergic disorders. Apitope was established at the University of Bristol in January 2002 by Professor David Wraith and initially funded by Mr Richard Daniels.

The company has a patented platform technology for the design of peptide therapeutics (Apitopes™) to treat autoimmune and allergic diseases. This novel Apitope technology is based on established scientific evidence showing that soluble, synthetic peptides can reinstate tolerance and attenuate pathological immune responses. The therapy is specifically designed from naturally occurring antigenic proteins to selectively inhibit the immune system's harmful attack on the body while preserving the normal immune response to harmful antigens, such as infections. The unique Apitope peptides function as tolerogens, exerting their therapeutic effect via an highly selective immune re-balancing process that, in pre-clinical studies, has been linked to the induction of IL-10 secreting regulatory T cells. Behaving as Antigen Processing Independent epiTOPES (Apitopes™), the peptides induce tolerance to abnormal immune responses.

The company, initially, is testing the safety and efficacy of Apitopes™ in multiple sclerosis (MS) patients. Its lead product is ATX-MS-1467, a peptide vaccine, which up regulates T cells through the major histocompatibility complex (MHC) class II receptor. The vaccine is potentially a disease-modifying therapy specifically designed from a naturally occurring antigenic protein to selectively inhibit the immune system's harmful attack on the nervous system. The normal immune response to infection is preserved. The ATX-MS-1467 vaccine is an equal parts mixture of four soluble, synthetic peptides (Apitopes™). The company plans to develop Apitopes™ for other chronic diseases including Type I diabetes, rheumatoid arthritis and the common allergies.

- Apitope's Phase I/IIa protocol for MS was approved by the MHRA in February 2007
- The Company is also developing an MS diagnostic, which is based on its proprietary technology, with a predicted launch date of Q4, 2009
- A peptide vaccine to prevent Factor VIII intolerance is expected to enter clinical trials in late 2008.

Apitope is backed by The Wellcome Trust, Sulis Seedcorn Fund and advised by Innovator Capital.

Further information on the company can be found at: <http://www.apitope.com/>

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